

REMARKS

These remarks are in response to the Final Office Action mailed July 9, 2003. Claims 18, 21 and 22 have been canceled without prejudice to Applicant's right to prosecute the canceled subject matter in any divisional, continuation, continuation-in-part, or other application. Claim 13 has been amended. Support for the amendment can be found, for example, at page 2, lines 20-21 and page 3, lines 1-7. No new matter is believed to have been introduced.

I. DEPOSIT REQUIREMENTS

The Office Action alleges that the deposit requirement for accession no. BP-7790 has not been met. It is alleged that the declaration and information provided in the file history does not indicate a "chain of custody".

Applicant submits that the Declaration by Dr. Sakaguchi clearly states, ". . .that the deposited material, FERM BP-7790, was in our possession at the time of filing of the instant application and that the deposited material is the same material as that described in the specification as the SKG strain." (See paragraph 5 of the Declaration filed April 17, 2003). Accordingly, this evidence demonstrates the chain of custody.

In addition, the Office Action alleges that page 3, lines 1-7, does not "describe the embryos deposited because it is a discussion generic to at least five types of mice disclosed in the specification in Example 1 (pg 5-6). . . ." (See the Office Action at page 2). Applicants respectfully submit that the specification at pages 5-6 (Example 1) are back-crosses

independent of the deposit and are provided to show allelic segregation. The deposited embryos comprise the SKG strain and not the back-crosses based upon the SKG strain.

Finally, the Office Action alleges that page 3, lines 1-7, does not teach that the SKG strain had rheumatoid arthritis or genes that cause natural onset of arthritis. Applicant submits that the claims have been amended to more clearly define the invention. ✓

II. REJECTION UNDER 35 U.S.C. §101

Claims 13, 18, 21, and 22 stand rejected under 35 U.S.C. §101 because the claims are allegedly directed to non-statutory subject matter. Claims 18, 21 and 22 have been canceled, thus the rejection is moot with respect to these claims. Applicants respectfully traverse this rejection.

The Office Action alleges that claim 13 encompass naturally occurring products. Applicant submits that the mouse or mouse strain is "obtained from an embryo deposited as accession no. FERM BP-7790 with the International Patent Organism Depository" and therefore does not encompass naturally occurring products. Accordingly, Applicant respectfully requests withdrawal of the §101 rejection.

III. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 13, 18, 21, and 22 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed had possession of the claimed invention. Claims 18, 21 and 22 have been

canceled, thus the rejection is moot with respect to these claims. Applicant respectfully traverses this rejection.

Applicant submits that claim 13 has been amended to more clearly define Applicant's invention. Applicant submits that the amendments render this rejection moot. Accordingly, Applicant respectfully requests withdrawal of the §112, first paragraph rejection.

Claims 13, 18, 21, and 22 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the claimed invention. The Office Action alleges that the deposit information provided in the prior response (Paper No. 18) did not fulfill the deposit requirements. Claims 18, 21 and 22 have been canceled, thus the rejection is moot with respect to these claims. Applicant respectfully traverses this rejection.

Applicant submits that the foregoing amendments and remarks under the §101 and §112 rejections above address this rejection. Applicant submits that the rejection may be properly withdrawn.

IV. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 10-20 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant submits that claims 10-12, and 14-20 are not pending. Claims 18, 21 and 22 have been canceled, thus the rejection is moot with respect

to these claims. Applicant respectfully traverses this rejection.

Applicant submits that the amendment to claim 13 overcomes this rejection. Accordingly, Applicant respectfully requests withdrawal of the \$112, second paragraph rejection.

V. REJECTION UNDER 35 U.S.C. §102

Claims 13, 18, 21, and 22 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg. 717-722). Applicant respectfully traverses this rejection.

As evidence of the patentability of the present invention, it should be noted that BALB/c mice were introduced in 1913 and, since then, have been used extensively in research; however, prior to Applicant's disclosure, there has been no report of a BALB/c mouse that, without being induced, will develop rheumatoid arthritis in the normal progression of its life ("natural onset" of rheumatoid arthritis). Furthermore, the claimed invention utilizes a deposited embryo having characteristics indicative of autoimmune arthritis that can be used to reproducibly obtain mice having such autoimmune arthritic conditions. This is neither taught or suggested by Nordling. Accordingly, Applicant respectfully requests withdrawal of the §102 rejection.

Claims 13, 18, 21, and 22 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Yamanaka et al. (U.S. Patent No. 4,950,741). Applicant respectfully traverses this rejection.

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention.

The Patent Office states that Yamanaka teaches a BALB/c mouse having a trait of developing rheumatoid arthritis.

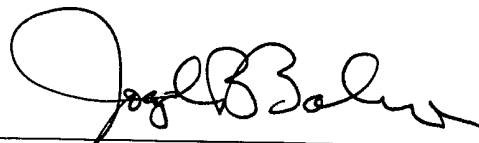
Applicant respectfully submits that Yamanaka does not teach a BALB/c mouse having a trait of developing rheumatoid arthritis. Yamanaka discloses a purified rheumatoid arthritis specific protein ("RASP") found in patients suffering from rheumatoid arthritis and anti-RASP antibodies. Yamanaka does not teach a BALB/c mouse having the trait of developing rheumatoid arthritis. Applicant respectfully submits that although mention is made of a BALB/c mouse in column 18, lines 1-10; however, it is only in the context of immunizing the mouse to obtain antibodies. Thus, Applicant submits that Yamanaka does not teach each and every limitation of the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the rejection based upon 35 U.S.C. §102.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: _____

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